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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/569,863

06/13/2006

Per Holm

20481/1206898-US1

9762

7278

7590

06/09/2009

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EXAMINER

POLANSKY, GREGG

ART UNIT

PAPER NUMBER

1614

MAIL DATE

DELIVERY MODE

06/09/2009

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<p align="center"><b>Advisory Action</b> <b>Before the Filing of an Appeal Brief</b></p>	<b>Application No.</b> 10/569,863	<b>Applicant(s)</b> HOLM ET AL.	
	<b>Examiner</b> GREGG POLANSKY	<b>Art Unit</b> 1614	

**--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

THE REPLY FILED 26 May 2009 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE.

1. ☒ The reply was filed after a final rejection, but prior to or on the same day as filing a Notice of Appeal. To avoid abandonment of this application, applicant must timely file one of the following replies: (1) an amendment, affidavit, or other evidence, which places the application in condition for allowance; (2) a Notice of Appeal (with appeal fee) in compliance with 37 CFR 41.31; or (3) a Request for Continued Examination (RCE) in compliance with 37 CFR 1.114. The reply must be filed within one of the following time periods:

- a) ☒ The period for reply expires 4 months from the mailing date of the final rejection.  
 b) ☐ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection.

Examiner Note: If box 1 is checked, check either box (a) or (b). ONLY CHECK BOX (b) WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### NOTICE OF APPEAL

2. ☐ The Notice of Appeal was filed on \_\_\_\_\_. A brief in compliance with 37 CFR 41.37 must be filed within two months of the date of filing the Notice of Appeal (37 CFR 41.37(a)), or any extension thereof (37 CFR 41.37(e)), to avoid dismissal of the appeal. Since a Notice of Appeal has been filed, any reply must be filed within the time period set forth in 37 CFR 41.37(a).

#### AMENDMENTS

3. ☒ The proposed amendment(s) filed after a final rejection, but prior to the date of filing a brief, will not be entered because  
 (a) ☒ They raise new issues that would require further consideration and/or search (see NOTE below);  
 (b) ☐ They raise the issue of new matter (see NOTE below);  
 (c) ☒ They are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or  
 (d) ☐ They present additional claims without canceling a corresponding number of finally rejected claims.

NOTE: See Continuation Sheet. (See 37 CFR 1.116 and 41.33(a)).

4. ☐ The amendments are not in compliance with 37 CFR 1.121. See attached Notice of Non-Compliant Amendment (PTOL-324).  
 5. ☐ Applicant's reply has overcome the following rejection(s): \_\_\_\_\_.  
 6. ☐ Newly proposed or amended claim(s) \_\_\_\_\_ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).  
 7. ☒ For purposes of appeal, the proposed amendment(s): a) ☒ will not be entered, or b) ☐ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.  
 The status of the claim(s) is (or will be) as follows:  
 Claim(s) allowed: \_\_\_\_\_.  
 Claim(s) objected to: \_\_\_\_\_.  
 Claim(s) rejected: 1,3-11,13-29,31-34,36,37,40-44 and 51-56.  
 Claim(s) withdrawn from consideration: 2,12,29 and 38.

#### AFFIDAVIT OR OTHER EVIDENCE

8. ☐ The affidavit or other evidence filed after a final action, but before or on the date of filing a Notice of Appeal will not be entered because applicant failed to provide a showing of good and sufficient reasons why the affidavit or other evidence is necessary and was not earlier presented. See 37 CFR 1.116(e).  
 9. ☐ The affidavit or other evidence filed after the date of filing a Notice of Appeal, but prior to the date of filing a brief, will not be entered because the affidavit or other evidence failed to overcome all rejections under appeal and/or appellant fails to provide a showing a good and sufficient reasons why it is necessary and was not earlier presented. See 37 CFR 41.33(d)(1).  
 10. ☐ The affidavit or other evidence is entered. An explanation of the status of the claims after entry is below or attached.

#### REQUEST FOR RECONSIDERATION/OTHER

11. ☒ The request for reconsideration has been considered but does NOT place the application in condition for allowance because:  
See Continuation Sheet.  
 12. ☐ Note the attached Information *Disclosure Statement*(s). (PTO/SB/08) Paper No(s). \_\_\_\_\_.  
 13. ☐ Other: \_\_\_\_\_.

/Ardin Marschel/  
Supervisory Patent Examiner, Art Unit 1614

/Gregg Polansky/  
Examiner, Art Unit 1614

Continuation of 3. NOTE: Claim 42 has been amended to require the release of at the most 10% of the active agent within the first 3 hours following administration. This amendment would require further consideration.

Continuation of 11. does NOT place the application in condition for allowance because: Without entry of the proposed amended claim set the 35 USC 112 2nd paragraph rejections and certain 35 USC 112 1st paragraph rejections of the previous Office Action are maintained. Applicants' arguments with regard to the 35 USC 112 1st paragraph New Matter rejection are not persuasive for reasons of record. Despite Applicants' assertion that the specification teaches evaporation of the organic solvent after preparation of a solid dispersion using the "solvent method", one of skill in the art would recognize that at least trace amounts of the solvent would remain in the dispersion; the specification provides no criteria by which one would consider what "free" of solvents encompasses. Furthermore, the claims are to a pharmaceutical composition which is free of organic solvent; there is nothing in the specification which prohibits introduction of organic solvent in process steps, such as, for example, coating a dosage form of the composition. The rejection of claims as being indefinite because of the phrases "between about", "from about" and "at least about" is maintained for reasons of record.

With regard to the Obviousness Rejection over Patel et al., Applicants argue that, although Patel et al. disclose poloxamer and PEG, there is no motivation to select these agents from the many possible components disclosed by Patel et al. This argument is not persuasive. Patel et al. teach poloxamers among the most preferred surfactants (paragraph 211) and is exemplified in Example 31. The use of PEG, including PEG 6000 is also exemplified (e.g., Example 30). The combination of 2 or more agents used previously for the same purpose is obvious. Applicants' argument with regard to superior bioavailability of the claimed tacrolimus composition has not been presented previously and would require further consideration.

Applicants have chosen to hold the Double Patenting Rejections of record in abeyance until a claim is found allowable.